

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Klaus Sommermeyer  
Application No.: 10/537,176 Group: 1623  
371 (c) Filing Date: September 2, 2005 Examiner: Scarlett Y. Goon  
Confirmation No: 8000  
For: ALDONIC ACID ESTERS, METHODS FOR PRODUCING THE SAME, AND  
METHODS FOR PRODUCING PHARMACEUTICAL ACTIVE  
INGREDIENTS COUPLED TO POLYSACCHARIDES OR  
POLYSACCHARIDE DERIVATIVES ON FREE AMINO GROUPS

CERTIFICATE OF MAILING OR TRANSMISSION	
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DECLARATION OF DR. KLAUS SOMMERMEYER UNDER 37 C.F.R. §1.132

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

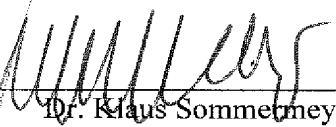
I, Dr. Klaus Sommermeyer, of In der Laubach 26, Rosbach, V.D.H. 61191, Germany, hereby declare and state as follows:

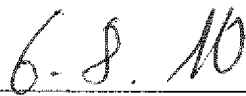
1. I am the sole inventor of the subject matter described in U.S. Application Serial No. 10/537,176 (hereinafter, the "Application") and a co-inventor in an International Application publication WO 2002/080979, the U.S. National stage of which is published as U.S. Publication No. US 2005/0063943 (hereinafter, "Sommermeyer").

2. Prior to making this Declaration, I have thoroughly read the above-identified application, the Office Action issued by the United States Patent & Trademark Office ("USPTO") on March 12, 2010 (hereinafter the "Office Action"), Sommermeyer reference cited in the Office Action and the pending claims. I have been asked to comment on experiments described in Sommermeyer and the comparison between an isolated aldonic ester of Claim 35 and the product obtained by the experiments described in Sommermeyer.
3. In the Office Action, the Examiner asserted that under conditions described in example 2 of Sommermeyer, stable esters of an aldonic acid can be obtained, albeit at a lower yield. The Examiner stated that Sommermeyer discloses in example 2 (paragraph [0147]) a compound, which is a product of the coupling reaction between hydroxyethyl starch (HES) oxidized at the reducing end and Human Serum Albumin (HSA) protein. The reaction is proceeding in water, in the presence of ethyldimethyl-aminopropyl-carbodiimide (EDC), as described and further exemplified in Table 2 (page 11 of Sommermeyer). Specifically, the Examiner asserts that *an isolated ester*, as defined in the Application on page 9 of the instant specification, can be formed as an intermediate when an acid (oxidized hydroxyethyl starch (ox-HES)) is reacted with EDC in the presence of 1-hydroxy-1H-benzotriazolhydrate (1-HOBt), as described in example 2 and Table 2.
4. The experiments described in example 2 and Table 2 of Sommermeyer were carried out either by me or under my supervision. The reaction of HES, oxidised at the reducing end, with EDC and HOBt according to example 2 of Sommermeyer was performed in an aqueous solution (paragraph [0147] of Sommermeyer). The reaction of HES, oxidized at the reducing end, with EDC and HOBt according to example 2 of Sommermeyer does not produce an "*isolated ester*", as claimed in Claim 35, since it is well known that such stable esters are only obtainable in anhydrous solvents. Under conditions disclosed in example 2,

very reactive intermediate *O*-acylisourea will be formed and not an ester. Therefore, it is not just that under the conditions of example 2 of Sommermeyer ester is not formed, but also the intermediate produced in the reaction of HES, oxidised at the reducing end, with EDC and HOBt, as described in example 2 cannot be isolated in even small amounts as the Examiner says. Therefore, example 2 of Sommermeyer does not disclose an isolated ester of an aldonic acid, as claimed in the Application.

5. I further declare that all statements herein of my own knowledge are true and that all statements made on information in belief are believed to be true; and further that the statements are made with the knowledge that willful false statements of the like so made are punishable by fine or imprisonment or both Under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereof.

  
\_\_\_\_\_  
Dr. Klaus Sommermeyer

  
\_\_\_\_\_  
Date